

RAINER KROPKE ET AL.
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Applicants do not believe that the new claims introduce new matter.

Claims 4-7 and 12-17 were rejected under 35 USC § 102(b) as being anticipated by FR 2667072. In response, Applicants point out that the claims require that the molecular weight of the "chitosan [has] an average molecular weight of from 100,000 to 1,000,000 and a degree of deacetylation of > 55 to 99%." While the fact that the cited patent may teach a molecular weight of "over 5,000," this teaching is not sufficiently specific to anticipate the claimed average molecular weight range of "100,000 to 1,000,000." As set forth in MPEP § 2131.03, the "sufficiently specific" standard "is similar to that of 'clearly envisaging' a species from a generic teaching." Applicants submit that there is absolutely no way, given the infinite possibilities, that a person having ordinary skill in the art, given a teaching of "over 5,000" would clearly envisage "100,000 to 1,000,000," as instantly claimed. Consequently, there is no anticipation.

Claims 4-7 and 12-17 were rejected under 35 USC § 103(a) as being obvious over EP 0 771 556, Magdassi or FR 2667072. In response, Applicants point out that none of the cited references expressly teaches Applicants' specific chitosans. Instead, there are only broad general references to molecular weights and degrees of deacylation. Most importantly, although these references do combine chitosans with phospholipids, the effect of the phospholipids on the

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tackiness of the composition is unstated. A person having ordinary skill in the art is, thus, not led by the teachings of any of these references to the reasonable expectation that the addition of phospholipids to a cosmetic or dermatological preparation comprising the specific chitosans presently claimed would have had the effect of either reducing the tackiness of such preparation or rendering it non-tacky. Absent that expectation, Applicants submit that none of these references taken alone or in combination makes out a *prima facie* case of the obviousness of the present methods.

According to *Manual of Patent Examining Procedure* ("MPEP") § 2143:

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

The question is, absent a technical anticipation, whether there is anything in the cited prior art that would have suggested to a person having ordinary skill in the art that phospholipids could or should be added to a cosmetic or dermatological preparation comprising the specific chitosans recited in the present claims to reduce the tackiness of such preparation or to render such preparation non-tacky? Applicants submit that there is absolutely nothing in the cited

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references taken alone or in combination that suggests this result. If person having ordinary skill in the art were setting out to reduce or eliminate the tackiness of a cosmetic or dermatological preparation comprising the specific chitosans required by the instant claims, he or she would not have been led by these references taken alone or in combination to add phospholipids for this purpose. Accordingly, the instant methods could *not* have been *prima facie* obvious to such persons.

The Examiner says at various points that "since the compositions are the same it would have been obvious to one of ordinary skill in the art that properties including non-tackiness would be the same." However, the Examiner has never shown the compositions to be the same. Indeed, Applicants have consistently argued that none of the compositions of the cited references teaches Applicants' chitosans. Since they do not teach Applicants' chitosans, the Examiner cannot presume identical properties.

With respect to the issue of inherency, it might be helpful for the Examiner to consider the decision in *In re Shetty*, 195 USPQ 753, 756-757 (CCPA 1977). The claims therein were drawn to a method of curbing appetite in animals by administering to the animals certain adamantane compounds. Certain similar compounds had previously been administered to animals, *but for other purposes*, i.e., to combat viral infections, to reduce blood sugar content and to treat depression. The Examiner therein reasoned that the claimed method was obvious because the compounds had previously been administered to animals in the same amount and, thus, the prior art technically taught the method step claimed.

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The Court, in response, held that the *purpose* that is to be achieved is a factor to be considered in the obviousness of a claimed method of use. Thus, on pages 756-757, the Court comments:

“The issue here is whether the claimed method of curbing appetite would have been obvious. That appellant’s ‘amount effective to curb appetite’ corresponds to or inheres in Narayanan’s amount ‘to combat microbial infestation’ does not persuade us of the obviousness of appellant’s method. As this court said in *In re Naylor* [citations omitted]:

*[Inherency] is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result. ****

*** we find nothing in the record which would afford one of ordinary skill reason to anticipate that a trial *** [of the combined prior art teachings] would be successful in producing the polymer recited in the claims.

The Patent Office has failed to show a reasonable expectation, or some predictability, that Brake’s compound *would be an effective appetite suppressant* if administered in the dosage disclosed by

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Narayanan. The mere hindsight assertion that corresponding dosages render appellant's method obvious is untenable. *Prior to appellant's disclosure, none of the adamantane compounds in any of the references suggested a use, much less a dosage, for curbing appetite.* What we said in *In re Spormann* [again, citations omitted], relative to inherency applies equally here:

As we pointed out in In re Adams [citations omitted], the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessary known. Obviousness cannot be predicated on what is unknown (emphasis added)."

As previously stated, there is nothing in the cited prior art that would have suggested to a person having ordinary skill in the art that phospholipids could or should be added to a cosmetic or dermatological preparation comprising the specific chitosans recited in the present claims to reduce the tackiness of such preparation or to render such preparation non-tacky. If person having ordinary skill in the art were setting out to reduce or eliminate the tackiness of a cosmetic or dermatological preparation comprising the specific chitosans required by the instant claims, he or she would not have been led by these references taken alone or in combination to add phospholipids for this purpose. Accordingly, the instant methods could *not* have been *prima facie* obvious to such persons.

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The Examiner says these arguments are unpersuasive because the specification does not provide a definition of reducing the tackiness or non-tacky in the specification. In response, Applicants submit that persons skilled in the art would understand exactly what these terms mean. "Reducing the tackiness" means making the preparation less tacky than it was before. "Non-tacky" means not tacky. Respectfully, the Examiner has not given any reason to doubt the meanings of these terms, or indicated why the failure to define these terms necessitates the Examiner ignoring Applicants' arguments.

The Examiner also says that Applicants have not demonstrated that the tackiness is reduced. In response, Applicants submit that Applicants are under no duty to make such a showing. The claims require that the preparation be rendered less tacky or non-tacky, and the Examiner must examine those limitations in the claims and show where they would have been obvious in the prior art. Clearly, this has not been done.

Finally, the Examiner says that Applicants have not shown the prior art compositions are sticky. However, as the proponent of this rejection, the burden was on the Examiner first to make out a *prima facie* case that the art teaches or suggests the addition of one or more phospholipids to a preparation for the purpose of rendering that preparation less tacky or non-tacky. Only when the Examiner has made out a *prima facie* case does the burden shift to Applicants to make any showings. Since the Examiner has not made out a *prima facie* case, Applicants were under no duty to make a showing.

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Claims 4-7 and 12-17 were rejected under 35 USC § 103(a) as being obvious over EP 0 771 556, Magdassi or FR 2667072 further in view of JP 63211208 or JP 03074316. In response, Applicants point out that they previously argued that there was no teaching in either of the JP references that phospholipids reduce tackiness. The Examiner responds by stating that "[t]his argument is not found persuasive since JP references state that the compositions are non-tacky and if the phospholipids have not contributed to the reduction of tackiness, the prior art compositions would have been tacky." In response, Applicants submit that the Examiner's conclusion does not follow. The Examiner has not shown that the compositions of the JP references contained tacky ingredients in the first place. Accordingly, it cannot be presumed that the phospholipids reduced the tackiness of such tacky ingredients or rendered them non-tacky. Moreover, even assuming for the sake of argument that the phospholipids did reduce the tackiness of such preparations, the preparations of the JP references appear to be fundamentally different from those instantly claimed, and, consequently, it cannot be presumed that the addition of phospholipids would have had a similar result in the instant preparations.

Respectfully, the Examiner would be fully justified to reconsider and withdraw all of the prior art rejections. An early notice that these rejections have been reconsidered and withdrawn is earnestly solicited.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

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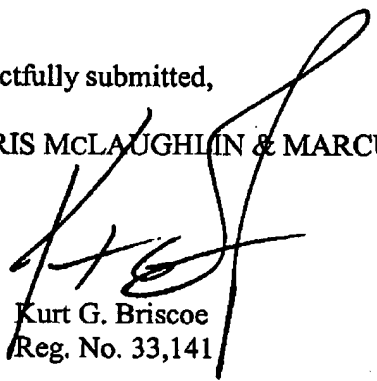
Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 and the accompanying Request for Continued Examination and Petition for Extension of Time (13 pages total) are being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: March 5, 2003

By


Kurt G. Briscoe